AWARD NUMBER:  W81XWH-16-1-0698

TITLE: A Novel Urinary Catheter with Tailorable Bactericidal Behavior

PRINCIPAL INVESTIGATOR:  Dr. Hassan Razvi

CONTRACTING ORGANIZATION: LONDON HEALTH SCIENCES CENTRE RESEARCH
London  N6C 2R5

REPORT DATE:  October 2017

TYPE OF REPORT:  Annual

PREPARED FOR:  U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland  21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and
should not be construed as an official Department of the Army position, policy or decision
unless so designated by other
**1. REPORT DATE**
October 2017

**2. REPORT TYPE**
Annual

**3. DATES COVERED**
30 Sep 2016 - 29 Sep 2017

**4. TITLE AND SUBTITLE**
A Novel Urinary Catheter with Tailorable Bactericidal Behavior

**6. AUTHOR(S)**
Dr Hassan Razvi
Dr Jeremy Burton

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) AND ADDRESS(ES)**
LONDON HEALTH SCIENCES CENTRE
RESEARCH I 750 BASE LINE RE LONDON N6C 2R5 CANADA

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**12. DISTRIBUTION / AVAILABILITY STATEMENT**
Approved for Public Release; Distribution Unlimited

**14. ABSTRACT**
This is a project being conducted at two sites. Our US collaborator’s role is the development of novel biomaterials that will be used to manufacture urinary catheters. Our portion of the project is the evaluation of these urinary catheters first in vitro, and then in an in vivo animal model. We have established animal protocols and written ethics in place to be able to undertake this work once we receive the materials from our research collaborator.

**16. SECURITY CLASSIFICATION OF:**
<table>
<thead>
<tr>
<th>a. REPORT</th>
<th>b. ABSTRACT</th>
<th>c. THIS PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unclassified</td>
<td>Unclassified</td>
<td>Unclassified</td>
</tr>
</tbody>
</table>

**17. LIMITATION OF ABSTRACT**
Unclassified

**18. NUMBER OF PAGES**
7

**19a. NAME OF RESPONSIBLE PERSON**
USAMRMC

**19b. TELEPHONE NUMBER (Include area code)**
None listed
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>4</td>
</tr>
<tr>
<td>2. Keywords</td>
<td>4</td>
</tr>
<tr>
<td>3. Accomplishments</td>
<td>4</td>
</tr>
<tr>
<td>4. Impact</td>
<td>5</td>
</tr>
<tr>
<td>5. Changes/Problems</td>
<td>5</td>
</tr>
<tr>
<td>6. Products</td>
<td>6</td>
</tr>
<tr>
<td>7. Participants &amp; Other Collaborating Organizations</td>
<td>6</td>
</tr>
<tr>
<td>8. Special Reporting Requirements</td>
<td>7</td>
</tr>
<tr>
<td>9. Appendices</td>
<td>7</td>
</tr>
</tbody>
</table>
1. **INTRODUCTION:**

Catheter-associated urinary tract infections (CAUTIs) are the most common nosocomial infection globally accounting for roughly 40% of all reported healthcare-associated infections (HAIs). Developing more biocompatible and infection-resistant urinary catheter materials may help to reduce the morbidity and mortality associated with CAUTIs. We believe that the proposed research has the potential to significantly reduce costs (product and care) and improve outcomes for military and civilian populations. In this project there are six specific aims that will be evaluated to test the silicone composite materials that employ a novel antimicrobial ion exchange (AM-IIE) resin system. Four of the aims are (*in vitro*) to be carried out at Iasis Molecular Sciences and are intended to optimize device configurations. Two specific aims to be carried out by ourselves (Razvi & Burton) are intended to evaluate the *in vivo* performance of these devices in a rabbit model.

2. **KEYWORDS:**

CAUTI, urinary tract infection, catheter, infection, silicone

3. **ACCOMPLISHMENTS:**

**What were the major goals of the project?**

Our contribution to the project is to test the novel polymers that have been developed using *in vitro* and *in vivo* evaluations. At this time we are awaiting delivery of the materials in order to begin our portion of the study. (Aims 4-8).

Specific Aim 1 – To synthesize coating polymers, identify an optimal lubricious coating, and optimize antiseptic loading
Specific Aim 2: Synthesis of AM-IIE resins, fabrication, and testing of ten composite silicone test articles
Specific Aim 3: In Vitro characterization of six AM-IIE silicone composites with antiseptic lubricious coating

**OUR AIMS START HERE**

---

**Specific Aim 4:** Determination of *in vitro* efficacy of the candidate composites
**Specific Aim 5:** *In vivo* rabbit ureteral stent model
**Specific Aim 6:** *In vivo* rabbit urethral catheter model
**Specific Aim 7:** Histopathological evaluation of kidney, bladder and ureter tissue samples
**Specific Aim 8:** Reporting and results evaluation for future clinical evaluations

---

**What was accomplished under these goals?**

We have derived animal protocols and ethics for our *in vivo* studies.
What opportunities for training and professional development has the project provided?

NA

How were the results disseminated to communities of interest?

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

Our part of the project will be well underway by this time next year. We anticipate we will have completed our in vitro studies, and the animal studies will be underway.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report.

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Actual or anticipated problems or delays and actions or plans to resolve them

Changes that had a significant impact on expenditures

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Significant changes in use or care of vertebrate animals.

Significant changes in use of biohazards and/or select agents
6. PRODUCTS

- List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."
  - Publications, conference papers, and presentations
  - Journal publications.
  - Books or other non-periodical, one-time publications.
  - Other publications, conference papers, and presentations.

Nothing to Report.

- Website(s) or other Internet site(s)
- Technologies or techniques
- Inventions, patent applications, and/or licenses
- Other Products

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- What individuals have worked on the project?

<table>
<thead>
<tr>
<th>Name:</th>
<th>Patricia Rosas Arellano</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Role:</td>
<td>Coordinator</td>
</tr>
<tr>
<td>Researcher Identifier (e.g. ORCID ID):</td>
<td>NA</td>
</tr>
<tr>
<td>Nearest person month worked:</td>
<td>3</td>
</tr>
<tr>
<td>Contribution to Project:</td>
<td>Dr Arellano has coordinated documents and protocols</td>
</tr>
<tr>
<td>Funding Support:</td>
<td>This award</td>
</tr>
</tbody>
</table>

- Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report.

- What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS
Nothing to Report.

9. APPENDICES

Nothing to Report.